Wisconsin Department of Health and Family Services

Pharmacy NewsCapsule

Division of Disability and Elder Services/Bureau of Quality Assurance (BQA) May/June 2003

Antipsychotic Medication Update

Doug Englebert
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Recently there have been questions raised about antipsychotic medications being used for non-approved symptoms or diseases. An example is the use of the new antipsychotic medications, Risperdal®, Zyprexa®, Seroquel®, Clozaril®, Abilify®, and Geodon®, for treatment of dementia with agitation. This is not an approved use of these medications. Often, physicians may use medications for diseases or symptoms that the US Food and Drug Administration (FDA) does not approve. When physicians use medications for non-approved uses, as in the above example, there is generally accepted literature to support the use for appropriate specific situations.

Concern arises when medications are prescribed for non-approved uses that are not generally accepted or supported by literature. For example, recently antipsychotic medications have been used for sleep, weight gain and pain management. This is not supported by literature.

As surveyors, your role is limited to assuring that the facility is appropriately monitoring the medication and justifying its use. For example, if an antipsychotic was given for weight gain, you should investigate and answer the following questions: Is the resident/patient actually gaining weight? Were other more generally accepted interventions attempted first? Is the resident/patient displaying negative effects of the medication? Is the facility monitoring for side effects? Beyond your surveyor role, you may find this practice objectionable. However, non-approved use without supporting evidence is not a violation of the regulations. The practice of using antipsychotics for unapproved, unsupported purposes does include risks. In fact, there are many lawsuits against facilities, physicians and drug companies when things go wrong with the inappropriate use of non-approved medications.

For example, in the case of antipsychotics, there is the risk of tardive side effects (tardive diskinesia, tardive dystonia).

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Insulin Updates

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Insulin Administration Update:
Regular insulin is recommended to be administered 30 minutes prior to a meal (drug package insert and American Diabetes Association [ADA] Guidelines). There are some new insulins (Humalog®, Novolog®) that can be administered 15 minutes before a meal, right before a meal or, in some cases, immediately after a meal. Please refer to specific product information, ADA Guidelines, and/or Surveyor Drug Review Guide for details on each specific product.

Exceptions to these general guidelines exist. Currently in an ADA book, Intensive Diabetes Management, timing of injections can be based on the blood sugar reading and the insulin being used. The site of injection can also affect absorption of insulin and timing may be adjusted depending on the site of injection. These exceptions to general guidelines reflect tight diabetes management and physician orders and/or care plans should reflect insulin injection timing.

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Inside This Issue

NOTE: March/April 2003 issue has been skipped

New Drugs

Doug Englebert Pharmacy Practice Consultant PRQI

Brand Name	Generic Name	Use
Emend	Aprepitant	Capsule for nausea and vomiting with chemotherapy
Fuzeon	Enfuvirtide	Injection for HIV
Amevive	Alefacept	Injection for Psoriasis

Med Error Corner-Nursing Home Focus

Doug Englebert Pharmacy Practice Consultant

As part of each nursing home survey, one task that is completed is the Medication Pass. In observing medications being administered, errors may be identified. These errors may be cited at 42 CFR 483.25(m) or survey tags F332 and F333. There are also medication errors that are not observed during the Medication Pass task. These are usually medication errors the survey agency has been made aware of through complaints. They may also be errors that are identified through the general investigation of the sampled residents' care. However, surveyors should **not** be sifting through records specifically looking for medication errors as part of the focused or comprehensive resident investigation.

Any citation that is issued for non-observed medication errors would not be cited at F332 or F333. The survey tags that should be considered to cite unobserved medication errors include F281, F309, F328, F426, F511, or F520. The determination of the tag that is used will depend on the specific circumstances of the medication error. For example, a medication error that has not been corrected that has resident outcome risks could be cited at F309. That citation should include evidence of the outcome or potential outcome risks.

Unobserved medication errors that have been corrected and that occurred at a time when the facility was in compliance (i.e., no outstanding citations) should be treated as past noncompliance. Therefore unobserved medication errors that occurred when the facility was in compliance, and where the system has been fixed would only be cited federally if the scope and severity was at a federal H level or higher. State code violations can be cited even if the facility has addressed the underlying problem.

Focus Drug of the Month

Doug Englebert
Pharmacy Practice Consultant PRQI

Zetia™;ezetimibe

This is a new medication that the Food and Drug Administration (FDA) has approved for the following uses:

- Reduction of low-density lipoprotein-cholesterol (LDL-C), total cholesterol, and apolipoprotein B when the drug is combined with dietary measures in the treatment of primary hypercholesterolemia.
- As combination therapy with statins (Mevacor®, Zocor®, Pravachol®, Lescol®, Baycol®, and Lipitor®) for the treatment of homozygous familial hypercholesterolemia.
- Reduction of elevated sitosterol and campesterol levels in the treatment of homozygous familial sitosterolemia.

Zetia™ works differently than other cholesterol lowering medications. It is currently known to inhibit the absorption of dietary and biliary cholesterol from the intestine, decreasing the amount of cholesterol delivered to the liver. This means that as the body absorbs less, the body can now remove more, decreasing cholesterol levels. Zetia™ has been shown to

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Antipsychotic Update - Cont. from Page 1

These side effects can be irreversible, extremely painful and can diminish the quality of life. In cases where physicians may be thinking of using an antipsychotic medication for sleep, to mitigate risk, the physician should assure that other safer, proven sleep medications should be tried first. Physicians should also assure that the patient/resident are fully informed of the risks of the antipsychotic (informed consent…a process not just a form). Physicians who do not follow this practice run the risk of malpractice lawsuits.

As surveyors, you must critically evaluate these situations. The unsupported use may reflect a careless approach to the use of antipsychotics and may not be monitored for effectiveness and side effects. Remember, non-approved medication used and monitored appropriately may not create a violation of the regulations.

In summary, surveyors may see antipsychotics used for the non-approved treatment of dementia with agitation. Your role is to assure that other medical, social and environmental causes of the dementia, such as agitation and other behaviors, have been ruled out. You should evaluate and determine if the behavior was persistent. Also, you should evaluate the impact on function to the patient or resident. When these three areas are not fully explored, the antipsychotic may be unnecessary. The unnecessary use runs a great risk of side effects, some of which can be irreversible. Your role is to assure that the facility has done the evaluation up-front before using the antipsychotic and once the choice was made to use an antipsychotic, ensure it is being properly monitored for the stated goals and unwanted side effects.

Insulin Update from page 1

Insulin Stability: Recently there has been information published addressing insulin expiration dates. Most of that information has been generally accepted and practiced in the health care community. However, insulin vials that are opened (punctured with a needle) and stored in a refrigerator after each use (drawing up of insulin) is controversial. In many cases the amount of insulin a patient or resident is using on a daily basis would not equal an entire vial in a 30 day period. In some cases the supply may last up to 90 days. When this occurs, healthcare professionals have recommended storing the vial in the refrigerator after each use. They have also recommended careful inspection of the vial prior to each use. **Therefore, at this time, for survey purposes, do not cite for vials used for longer than 30 days if the vials have been refrigerated after each use and are inspected prior to use.** Stay tuned for updates on this issue.

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Focus Drug of the Month

decrease LDL-C (bad cholesterol) on average by 17 percent. Compared to the statins, that generally can lower bad cholesterol by 30-40 percent, Zetia™ has a modest effect. In many cases this drug will be used in addition to a statin. For example, in many cases when a statin is started at the lowest dose, there will be a 30 percent or greater reduction in bad cholesterol. As the dose is doubled, an additional 5-7 percent decrease in bad cholesterol may be seen but the risk of side effects, especially in the elderly, increases. Therefore, a better option may be to take the statin along with Zetia™, as the Zetia™ may provide an additional 17 percent decrease compared to the 5-7 percent increase of doubling the statin dose. The approach of adding Zetia™ is cost neutral and may have less side effects.

Zetia™ comes as a 10 mg tablet given once a day. It can be administered with or without food at any time of day. The tablet can be crushed if necessary.

Zetia™ has some drug interactions. It should not be given with Lopid®, Tricor®, or fibrates. If cholestyramine is being used to also lower cholesterol and triglycerides, then Zetia™ should be given 2 hours before, or 4 hours after, cholestyramine has been given. Surveyors should be aware of the cholestryamine concern.
Side effects are minimal and include headaches, upper respiratory infections and gastrointestinal discomfort being noted at a high level. This is a newer agent and all adverse effects of this drug are yet unknown.

If there are medications you would like featured in this column, please send an email to Doug at engleda@dhfs.state.wi.us

Consultant's Corner

Doug Englebert *Pharmacy Practice Consultant PRQI*

This section will appear in each issue and will contain information that will answer your questions. If there is a topic about which you want more detailed information, please drop me an email at engleda@dhfs.state.wi.us and I'll research the topic.

1. ***Can family members bring in medications for patients and residents to take or staff to administer?***

Some facility regulations may not allow families to bring in medications. For example, regulations in nursing homes require the nursing home to assure medications are ordered, safe and come from pharmacies. To meet these regulations, medications are not allowed to be brought in by family members. In some cases regulations may not specifically address medications that are brought in by family members. In cases where facility staff are required to administer the medications, the facility may have liabilities with administering medications brought in by families. Therefore, facilities may have policies addressing this practice. For example, many hospitals will have policies addressing medications brought in by the patient or family. These policies will address when it is appropriate, how they will be stored, how they are administered, etc. In virtually all cases, the concern with medications brought in by the patient, resident or family is that the medications the facility received are those ordered and are in good condition.

2. ***Does the proton pump inhibitor need to be given with a meal?***

Many times physicians will not specify in their order to give a medication a specific way. Yet in many cases there are specific ways a medication should be given to optimize the benefits of the medication. Pharmacists should be providing that information to providers, patients and residents as a way to improve drug therapy. Proton pump inhibitors (Nexium®, Prilosec®, Prevacid®, Protonix®) are usually ordered once or twice a day. Usually the physician will not specifically indicate that the proton pump inhibitor be given with a meal. However, many pharmacists will recommend giving the medication ½ hour before a meal, as the medication tends to work better when administered that way.

3. ***What is Tarvil?***

Tarvil is a medical food supplement used for treating tardive dyskinesia. Its effectiveness in clinical practice is unknown.

4. ***Do facilities need to have a risk benefit statement?***

Often statement of deficiencies (SOD) for nursing homes will have statements to the effect that the facility did not have a risk/benefit statement in the chart for use of a medication. This statement is usually a confirmation that there was no evidence available to support the use of the medication. Specifically, evidence was lacking that indicates the drug is appropriate for the dose and duration for which it is being used, or that the drug is being used even though adverse reactions may be occurring.

Facilities are required to demonstrate evidence that the benefits of a drug outweigh the negative impact of the drug. That evidence does not have to be a very specific written statement. Evidence basically includes the entire record. Therefore, evidence could be: the MDS showing functionally improved, remained stable, or improved; monitoring of side effects that are documented; and physical characteristics of the resident or patient.

The SOD should reflect that the evidence is missing. The SOD should avoid indicating that no risk/benefit statement was present. Those statements lead to citations that may be dropped, as they are not specific to the evidence that was not present. Those statements also lead to plans of corrections where the facility simply asks the physician to write this specific statement which may duplicate work etc., and brings no value to the resident.

References are available upon request.